SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K 033274
TECHLAB GIARDIA 11

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I device. The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   The changes identified were as follows:

   1. A direct format replaced an indirect format making the test simpler to perform. The detecting antibody is directly labeled with horse radish peroxidase thereby eliminating the anti rabbit IgG:HRP conjugate
   2. A two component substrate was replaced by a one component substrate. Both contain the same two chemicals namely tetramethyl benzidine and peroxide.
   3. Stop solution was weakened from 1M sulfuric acid to 0.6 N (equiv. to 0.3M) sulfuric acid.
   4. A sample diluent (buffered protein solution with 0.02% Thimerosal) is included for use.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and performance characteristics which included a comparison of this device test results to the legally marketed predicate device using 110 positive and 93 negative specimens in one study and 88 positive and 40 negative specimens in another study; reproducibility, freeze-thaw and crossreactivity studies.

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

Following are the **Acceptance Criteria** used to determine a successful validation:
Evaluate each test based upon the following specifications and refer to the diagram following.

Giardia Cysts Standard Curve (Plate 1-strips 1 & 2)
Rows A -D: Must be positive, ≥ 0.150 OD $_{450}$ and/or ≥ 0.090 OD$_{450/620}$
Rows E - H: May vary between positive and negative

rCWP1 Antigen Standard Curve (Plate 1-strips 3 & 4)
Rows A - D: Must be positive, ≥ 0.150 OD $_{450}$ and/or ≥ 0.090 OD$_{450/620}$
Rows E - H: May vary between positive and negative

Positive Control (Plate 1 - strip 5 Plate 2 - strip 5)
Rows A - H: All wells must be positive, ≥ 1.000 OD $_{450/620}$ and OD$_{450}$
All wells must display a yellow color

Negative Control (Plate 1-strip 6, Plate 2-strip 4)
Rows A - H: All wells must be negative, < 0.150 on OD $_{450}$ and/or < 0.090 OD$_{450/620}$ All wells must be visually clear

Eight Positive Fecals (Plate 2 - strip 1)
All wells must be positive, ≥0.150 OD $_{450}$ and/or ≥0.090 OD$_{450/620}$

Sixteen Negative Fecals (Plate 2- strips 2 & 3)
All wells must be negative, < 0.150 OD $_{450}$ and/or < 0.090 OD$_{450/620}$

Plate 1

Giardia Cysts/mL		rCWP1 Antigen ng/mL		Pos. Ctr.	Neg. Ctr.						
1	2	3	4	5	6	7	8	9	10	11	12
150,000	150,000	25	25	+	-						
15,000	15,000	12.5	12.5	+	-						
1,500	1,500	6.25	6.25	+	-						
750	750	3.13	3.13	+	-						
375	375	1.56	1.56	+	-						
188	188	0.78	0.78	+	-						
94	94	0.39	0.39	+	-						
47	47	0.2	0.2	+	-						

Plate 2

+ Fecals formalin	- Fecals formalin	- Fecals unpreserved	Neg. Ctr.	Pos. Ctr.
1	2	3	4	5
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+
+ F	- F	- F	-	+

c) A declaration of conformity with design controls. The declaration of conformity should include:
   i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
   ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A **Truthful and Accurate Statement**, a **510(k) Statement** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular

modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, it is recommended that the device be determined substantially equivalent to the previously cleared device.